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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,330	06/23/2003	Clarence Nathaniel Ahlem	202.2D2	9052

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
07/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/602,330	AHLEM ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119,121,123 and 132* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119,121,123 and 132* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 119, 121, 123 and 132 are pending in the present application.

3. The rejection of claims 120, 122, 124-131 and 133-146 under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination is made moot by the cancellation of the instant claims.

4. The rejection of claims 119, 121, 123 and 132 under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination is maintained.

Applicant argues the cited references do not disclose the specific drug treatment regimen recited by the claims, i.e., 5 consecutive daily doses of 3β,17β-dihydroxyandrost-5-ene, intramuscular administration and specific dosages that resulted in increased neutrophil numbers in humans in phase 1 safety studies. Applicant also argues (a) Carr makes no suggestion as the ability of the compound to increase neutrophils and, thus, in combination does not suggest any protocol or dosage that would necessarily result in a neutrophil increase in humans, (b) the function of 3β,17β-

dihydroxyandrost-5-ene was not known and the cited references lead to no identified "design need or market pressure" that would lead the skilled artisan to contemplate the subject matter of the amended claims, (c) the discovery of a problem can lead to patentability, even if the solution to the problem was obvious; (d) neutrophil response seen in humans is not "inherent to the compound" and (e) innate immune suppression does not always occur in the various clinical conditions the cited references describe. Applicant's argument was considered but not persuasive for the following reasons.

The instant claims are drawn to a method of treating or ameliorating innate immune suppression by the intramuscular administration of 200, 250 or 300 mg of 3β,17β-dihydroxyandrost-5-ene once a day for 5 consecutive days. The instant claims also recite said innate immune suppression is associated with radiation and the treatment of amelioration is due to an increase in the number of neutrophils in circulation.

The prior art teaches utilization of the claimed compound for enhancing the protective response of the immune system against immune suppressive influences, for example, radiation. The art also teaches that (a) dosages used will be dependent on the size and condition of the host (see '042, col. 17, lines 38-40); (b) dosages of 32-320 mg/kg given subcutaneously have immunomodulatory effects (see Carr, Abstract) and (c) various routes of administration including intradermal injection (see '042, col. 4, lines 50-54).

Based on the teachings of the prior art as discussed above and in the previous Office Actions, the utilization of 3β,17β-dihydroxyandrost-5-ene to enhance the

protective response of the immune system against suppressive influences as seen with radiation would have been obvious to the skilled artisan in the art at the time of the present invention. The dosages recited by the instant claims would also be obvious based on the prior art teachings and the level of skilled of the ordinary artisan in the art. Additionally, it would require only routine experimentation to determine the dosage of 3β,17β-dihydroxyandrost-5-ene useful in protecting the immune system against immune suppressive influences. The recitation of the limitation of "once daily for 5 consecutive days", is not a patentable distinction since said the determination of treatment regimen is routine in the medical art (see discussion in previous Office Action).

Applicant's argument centers around the discovery that the administration of 3β,17β-dihydroxyandrost-5-ene results in increase in neutrophil numbers in circulation. However, the examiner maintains that said activity is inherent to the compound and, thus, its discovery does not lend patentability to the claimed treatment method. The examiner notes applicant's argument that neutrophil response is not inherent to the compound. Contrary to applicant's assessment and as shown by applicant, the administration of the compound does increase neutrophil numbers in circulation and, thus, said property is associated with the administration of the compound. The fact that said increase in neutrophil numbers might be dose dependent does not change the fact that the increase in neutrophil number is an inherent property of the 3β,17β-dihydroxyandrost-5-ene.

In summary, the discovery of a new activity of a known compound does not lend patentability to the utilization of said compound in a known method of using said

compound. See In re May, 574 F. 2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). There is no requirement that the prior art arrives at the claimed treatment method by solving the problem discovered by applicant.

For these reasons and those given in previous Office Actions, the rejection of claims 119, 121, 123 and 132 under 35 USC 103(a) over Lorie (US 5,461,042 or US 5,387,583) in view of Carr (J. Neuroimmunology, 1998) in combination is maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612